

## TEXT OF REGULATIONS

### ARTICLE 1. DEFINITIONS

(1) Adopt §6500.03 to read:

**§6500.03. California Children's Services (CCS).**

"California Children's Services (CCS)" means a State and County program providing medically necessary benefits as defined in Title 22, Division 2, Subdivision 7, Chapter 1, §41452 to persons under 21 years of age with physically handicapping conditions who meet medical, financial and residential eligibility requirements for the CCS program.

Note: Authority cited: Sections 20, 100275, 123805, 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 123830, 123835, 123845, 123865, 123870, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(2) Adopt §6500.05 to read:

**§6500.05. Confirmatory Test.**

“Confirmatory Test” means a laboratory test done to prove or disprove the presence of a specific condition identified by the newborn screening test. This test is performed on a specimen other than the screening specimen.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(3) Adopt §6500.9 to read:

**§6500.9. Early Specimen.**

“Early Specimen” means a newborn screening specimen collected from a newborn who is less than 12 hours of age.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(4) Adopt §6500.21 to read:

**§6500.21. Infant.**

“Infant” means a child 29 days through 12 months old.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124116, 124975, 124980, 125000, 131050, 131051 and 131052,  
Health and Safety Code.

(5) Adopt §6500.33 to read:

**§6500.33. Lost to Follow-Up.**

“Lost to Follow-Up” means the inability of the Newborn Screening Area Service Center to locate the newborn or infant for follow-up because:

(a) there is no response to attempts to locate the parents or legal guardian after a minimum of 1 phone call and 1 certified letter using available contact information; and

(b) the Newborn Screening Area Service Center and the Department believe that reasonable attempts have been made to locate the infant.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(6) Amend §6500.35 to read:

**§6500.35. Newborn.**

“Newborn” means a child less than 29 days old ~~an infant 30 days of age and under.~~

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124116, 124975, 124980, 125000, 131050, 131051 and 131052,  
Health and Safety Code.

(7) Amend §6500.39 to read:

**§6500.39. Newborn's Physician.**

"Newborn's Physician" means the physician caring for the newborn or infant in the perinatal licensed health facility's normal newborn nursery or neonatal intensive care unit or in the outpatient community after discharge ~~responsible for the care of the newborn after discharge from the hospital.~~

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(8) Adopt §6500.43 to read:

**§6500.43. Newborn Screening.**

“Newborn Screening” means the testing of infants to identify those at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.



(9) Amend §6500.45 to read:

**§6500.45. Newborn Screening Area Service Center.**

~~“Newborn Screening Area Service Center” means an institution, corporation, hospital or university medical center:~~

~~(a) Having specialized expertise;~~

~~(b) Designated by the Department to serve a specific geographic area of the State; and~~

~~(c) Contracted with the Department to provide follow-up, referral and diagnosis of a preventable heritable or congenital disorder.~~

“Newborn Screening Area Service Center” means a facility which is contracted with the Department to provide regional newborn screening services.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(10) Adopt §6500.50 to read:

**§6500.50. Newborn Screening Specimen.**

“Newborn Screening Specimen” means a blood sample taken from an infant that is collected on a special filter paper purchased from the Department.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(11) Adopt §6500.51 to read:

**§6500.51. Newborn Screening Test.**

“Newborn Screening Test” means a biochemical or other assay of blood spots collected from an infant for the purpose of determining whether the newborn might be at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(12) Adopt §6500.55 to read:

**§6500.55. Out-of-Hospital Newborn Screening Providers.**

“Out-of-Hospital Newborn Screening Providers” means:

(a) all healthcare professionals including, but not limited to, licensed midwives (LM), certified nurse midwives (CNM), registered nurses (RN), physician assistants (PA), pediatric nurse practitioners (PNP), physicians/medical doctors (MD), doctors of osteopathy (DO), and naturopathic doctors (ND), who are licensed or certified by the State to provide maternal care and to deliver pregnant women in alternative settings other than perinatal licensed health facilities including, but not limited to, private homes and clinics; and

(b) staff of health care entities, such as clinics and free-standing independent laboratories that are authorized by the Department to collect newborn screening specimens in alternative settings other than perinatal licensed health facilities.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(13) Adopt §6500.58 to read:

**§6500.58. Perinatal Licensed Health Facility Staff.**

“Perinatal Licensed Health Facility Staff” means the individuals working in the laboratory, maternal, or nursery departments of perinatal licensed health facilities who collect the newborn screening specimens.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(14) Repeal §6500.65 as follows:

**~~§6500.65. Recall Specimen.~~**

~~"Recall specimen" means a specimen collected from a newborn because the initial test or combination of tests was positive for any of the disorders covered by this Group.~~

~~Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.~~

~~Reference: Sections 124980 and 125000, Health and Safety Code.~~

(15) Repeal §6500.67 as follows:

**~~§6500.67. Recall Test.~~**

~~"Recall test" means a test ordered collected from a newborn because the initial test or combination of tests was positive for any of the disorders covered by this Group.~~

~~Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.  
Reference: Sections 124980 and 125000, Health and Safety Code.~~

(16) Adopt §6500.71 to read:

**§6500.71. Screening Information System (SIS).**

“Screening Information System (SIS)”, in this Group, means the Department Newborn Screening Program’s database and associated screens that:

(a) list the newborn screening specimens that have been received by the Department for testing; and

(b) provide for reporting of those specimens that are missing.

This system is to be used to verify receipt of specimens and report those that have not been received pursuant to §6506.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.  
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.



(17) Adopt §6500.78 to read:

**§6500.78. This Group.**

“This Group” means Group 3. Newborn Screening Program in the official California Code of Regulations as follows: Title 17. Public Health, Division 1. State Department of Health Services, Chapter 4. Preventive Medical Service, Subchapter 9. Testing for Heritable Disorders, Group 3. Newborn Screening Program.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

## ARTICLE 2. TESTING AND FOLLOW-UP PROGRAM REQUIREMENTS

(18) Amend §6501 to read:

### **§6501. Scope of Newborn Testing.**

Except for provisions in §6501.2 and §6502, Each newborn born in California shall be tested for galactosemia, hereditary hemoglobinopathies, phenylketonuria, and primary congenital hypothyroidism and disorders authorized for testing in Health and Safety Codes 124977, 124980 and 125001 in accordance with procedures in this Group.

Note: Authority cited: Sections 124977, 124980, 124996, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, and 125025, 131050, 131051 and 131052, Health and Safety Code.

(19) Adopt §6501.5 to read:

**§6501.5. Required Newborn Screening Forms.**

The following newborn screening forms from the Department shall be utilized in accordance with provisions in this Group:

(a) For all newborn screening specimen collection pursuant to §6505(a)(1), §6505(a)(2), §6505(b)(1), §6505(b)(2), §6505(c)(1), §6506, §6506.6(a), §6506.6(b)(1) and §6506.6(c)(1): CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D). This form is hereby incorporated by reference.

(b) For parents or legally appointed guardians who object to a newborn screening test pursuant to §6501.2: NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) - English version or CDPH 4459(SP) (6/11) - Spanish version. This form is hereby incorporated by reference.

(c) For perinatal licensed health facility staff or birth attendants who have not obtained a newborn screening specimen pursuant to §6505(a)(4), §6505(b)(4) or §6506.2: HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS – NO) CDPH 4089 (01/11). This form is hereby incorporated by reference.

(d) For county registrars who register infants born outside of a perinatal licensed health facility or who are not attended by a birth attendant pursuant to §6505(d): NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09). This form is hereby incorporated by reference.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(20) Amend §6505 to read:

**§6505. Collection of Newborn Screening Specimens.**

~~(a) Birth attendants, laboratories and hospitals shall collect specimens using the technique for blood collection distributed by the Department.~~

~~(b) Physicians or birth attendants who are caring for newborns born in perinatal licensed health facilities shall have blood specimens collected using Department-approved specimen collection forms in accordance with criteria distributed by the Department including the following:~~

~~(1) A specimen must be collected from any untested infant prior to blood transfusion.~~

~~(2) For newborns discharged before six days of age, a blood specimen shall be obtained as close to the time of discharge from the perinatal licensed health facility as is practical regardless of age or feeding history, unless the newborn is transferred for continuing care to another perinatal licensed health facility on or before the sixth day of age. Perinatal licensed health facilities which discharge infants before 24 hours of age may request a waiver from this requirement documenting how such newborns will be tested on or before 6 days of age. Such alternative testing schedules must be approved in writing by the Department.~~

~~(3) For newborns remaining in perinatal licensed health facilities beyond five days of age, a blood specimen shall be obtained from the newborn on the sixth day of age regardless of feeding history.~~

~~(4) For newborns received by transfer on or before six days of age, the receiving hospital shall obtain a blood specimen as close to discharge as possible, and if not discharged by the sixth day, a blood specimen shall be obtained on the sixth day of life.~~

~~(c) For newborns not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility within the first six days of age, a specimen shall be obtained as close to discharge as possible, and if not discharged by the sixth day of life, a blood specimen shall be obtained on the sixth day of life unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.~~

~~(d) For newborns not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility after six days of age but within the first 30 days of age, a blood specimen shall be obtained within 48 hours after admission unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.~~

~~(e) Physicians attending sick newborns who exhibit symptoms suggestive of galactosemia, hypothyroidism or phenylketonuria (PKU), in addition to immediate diagnostic tests from local laboratory sources, shall have a blood specimen collected from the newborn and submitted to a newborn screening laboratory using forms purchased from the Department.~~

~~(f) Physicians attending critically ill newborns who require special care may postpone collection of a blood specimen until the newborn's emergency life threatening condition is stabilized.~~

~~(g) Birth attendants or physicians attending newborns not born in a perinatal licensed health facility and not subsequently admitted to a licensed health facility during the first six days of age, shall have a blood specimen collected from the newborn between the~~

~~second and sixth days of age and submitted to a newborn screening laboratory using forms obtained from the Department.~~

~~(h) If a newborn is born outside of a perinatal licensed health facility and the birth is not attended by a birth attendant and the newborn is not subsequently admitted to a perinatal licensed health facility within the first ten days of age, the person required to register the birth shall arrange for a blood specimen to be collected and submitted to a newborn screening laboratory between the second and tenth day of age.~~

~~(i) Initial specimens shall be collected using a Department-approved form and shall be placed in the United States mail or other approved channel of transmittal to the assigned Department-approved laboratory as soon as possible, but not later than 12 hours after they are obtained.~~

(a) For each newborn born in a perinatal licensed health facility, the perinatal licensed health facility staff shall:

(1) collect the newborn screening specimen, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b). This specimen collection shall occur after 12 hours but no later than 96 hours of age prior to discharge or transfer of the newborn unless the newborn's condition is life-threatening and the collection cannot be done safely. Physicians attending critically ill newborns who require special care may postpone collection of a newborn screening specimen until the newborn's emergency condition is stabilized. The receiving perinatal licensed health facility staff shall then collect the newborn screening specimen using the Instructions for Collecting Adequate Blood

Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM

(NBS-TRF) (CDPH – 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b)

as soon as the newborn's condition is stabilized. Any specimen collected on a newborn prior to 12 hours of age is an early specimen and another specimen shall be collected after 12 hours of age pursuant to §6505(a)(2) and §6506.6.

(2) collect a newborn screening specimen prior to red blood cell transfusion when the newborn is stable, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH – 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to §6501.5(c), in the event the newborn screening specimen is not collected prior to transfer to another perinatal licensed health facility and there is no copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409- (11-12)) NBS-I (D) in the newborn's medical record.

(5) Collection of a newborn screening specimen under this section shall not apply if the parent or legal guardian has signed a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) pursuant to 6501.5(b).



(b) For infants not born in a perinatal licensed health facility, but admitted to a perinatal licensed health facility at any time after birth, the perinatal licensed facility staff shall:

(1) obtain a newborn screening specimen within 48 hours of admission, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b), unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D), or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11), or a newborn screening result is found in the infant's medical record or the physician has a record of the screening specimen having been collected.

(2) collect a newborn screening specimen prior to red blood cell transfusion, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to 6501.5(c), in the event the newborn screening specimen is not collected.

(c) For infants not born in a perinatal licensed health facility and not admitted to a perinatal licensed health facility after birth, out-of-hospital newborn screening providers shall:

(1) collect a newborn screening specimen within 48 hours of the first contact with the infant using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11), or a newborn screening result is found in the infant's medical record.

(2) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(d) For infants born outside of a perinatal licensed health facility and not subsequently admitted to a perinatal licensed health facility, when the birth is being registered at the county registrar's office, the person in the county registrar's office required to register the birth shall notify the Department of the birth the next business day after the birth is registered using the NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09) pursuant to §6501.5(d).

(e) A newborn screening specimen may be collected on a child over 1 year of age with prior authorization from the Department.

(f)(i) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers without identifying the person or persons from whom these results were obtained, ~~unless the person or his/her legally authorized representative specifically prohibits such use in writing.~~

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(21) Amend §6506 to read:

**§6506. Medical Record Review~~Verification of Receipt of Newborn Screening~~**

**Specimens by the Department.**

~~(a) Perinatal licensed health facilities shall review each newborn's medical record within 14 days from the date of discharge to determine that the results of required tests are filed in the newborn's medical record, or that a parent's or legal guardian's signed refusal has been filed in the newborn's medical record.~~

Perinatal licensed health facility staff and out-of-hospital newborn screening providers shall check the Department Screening Information System (SIS) within 7 days after the date of birth to verify that the newborn screening specimen has been received by the Department. This applies to all infants for whom perinatal licensed health facilities and out-of-hospital newborn screening providers have responsibility for newborn screening pursuant to §6505(a), (b) and (c). If a specimen has not been received and there is neither a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) nor a copy of a completed NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) - English version or CDPH 4459(SP) - Spanish version pursuant to §6501.2 and 6501.5(b) present in the newborn's medical record, the staff shall complete a HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS – NO) CDPH 4089 (01/11) pursuant to §6501.5(c). If a specimen has not been received and the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) is present in the newborn's medical record, staff shall enter a missing specimen report into the Screening Information System (SIS), and

if the newborn has not been discharged, collect a newborn screening specimen on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) within 24 hours.

This specimen shall be given to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory on the next business day of the designated carrier.

~~(b) Whenever a perinatal licensed health facility determines that a specimen has been obtained, but there are no results available in the newborn's medical record, the facility shall send written notification within five days to the Department.~~

If a perinatal licensed health facility or a group of perinatal licensed health facilities has an internal computerized system in place to identify specimens received by their designated newborn screening laboratory, and this system has the same criteria to verify receipt of newborn screening specimens as the Department's Screening Information System (SIS) as described in §6500.71(a) and (b), then their system rather than SIS may be used to verify receipt of their specimens.

Note: Authority cited: Sections 124977, 124980, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 12500~~1~~, and 125025, 131050, 131051 and 131052, Health and Safety Code.

(22) Amend §6506.6 to read:

**§6506.6. Follow-Up to Reports of Inadequate and Early Newborn Screening  
Specimens.**

~~When the newborn's physician is notified by the laboratory by telephone that a specimen is inadequate, the physician so notified shall make every reasonable effort to have an adequate specimen obtained within five days of notification. If the newborn's physician so notified, cannot obtain the repeat specimen, the physician shall notify the Newborn Screening Area Service Center as soon as possible by telephone. Such telephone notification shall be noted in the newborn's physician's records specifying the date of notification, the person notified and the information provided.~~

(a) For those specimens identified by the Newborn Screening Area Service Center as early, or where the infant's age at time of specimen collection cannot be determined, the Newborn Screening Area Service Center shall verify with the collecting person or facility the dates and times of birth and specimen collection written on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D).

(b) Upon notification by the Newborn Screening Area Service Center that the specimen is verified as an early specimen, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by the United States Postal Service to the assigned newborn screening laboratory.

(c) When the perinatal licensed health facility staff, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician is notified by the Newborn Screening Area Service Center that a specimen is an inadequate specimen, the perinatal licensed health facility, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by the United States Postal Service to the assigned newborn screening laboratory.

(d) If a repeat specimen for either an early or an inadequate specimen cannot be obtained, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall notify the Newborn Screening Area Service Center by phone, fax, or e-mail within 48 hours regarding the status of the collection and also again when the specimen has been collected and sent to the Department.

(e) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, ~~and~~ 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, ~~and~~ 125025, 131050, 131051 and 131052, Health and Safety Code.



(23) Amend §6506.8 to read:

**§6506.8. Follow-Up to Reports of Initial Positive Results.**

~~When the newborn's physician is notified by telephone by the Department-approved Newborn Screening Area Service Center of an initial positive test result, the newborn's physician shall obtain an adequate recall blood specimen from the newborn and submit it to the designated laboratory within 48 hours. If the recall specimen cannot be obtained within 48 hours, the newborn's physician shall notify the Newborn Screening Area Service Center by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the date of notification, the person notified and the information provided.~~

(a) When the newborn's physician is notified by a Newborn Screening Area Service Center of a positive test result, the physician shall, within 48 hours of notification:

(1) Consult with a medical specialist from a California Children's Services (CCS) center or a CCS-paneled medical specialist, and upon the specialist's advice, shall refer the infant to a CCS center or a CCS paneled medical specialist for confirmatory testing and/or evaluation, diagnosis, and treatment; and

(2) Instruct the parents about medically necessary recommendations to care for the infant.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, ~~and 125025~~, 131050, 131051 and 131052, Health and Safety Code.

(24) Amend Section 6506.10 to read:

**§6506.10. Use of Newborn Screening Contracted Laboratories for Repeat and Recall Confirmatory Specimens Collection and Transmittal.**

~~Repeat and recall specimens required by this Group shall be collected on Department approved forms, placed in appropriate containers, and shall be placed in the United States mail or other approved channel of transmittal to the assigned Department-approved laboratory as soon as possible, but not later than 12 hours after they have been obtained.~~

(a) When repeat or confirmatory tests are required, the newborn's physician will ensure that:

(1) Repeat or confirmatory specimens are collected within 48 hours;

(2) Specimens are placed in containers appropriate for the specified test; and

(3) Specimens are transported, on the next business day of the designated carrier, by a carrier contracted with the Department or contracted with a newborn screening laboratory or by the United States Postal Service, to the assigned newborn screening laboratory.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, ~~and~~ 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, ~~and~~ 125025, 131050, 131051 and 131052, Health and Safety Code.